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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers's Lane, rm. 1061
Rockville, MD 20852y

Dear Sirs:

Permit me to provide comments on the proposed rule regarding Suitability Determination for Donors of Human Cellular and Tissue-based Products (Docket No. 97N-484S) as listed in the Federal Register, Volume 64, Number 189, September 30,1999, Pages 52696-52723. Permit me to offer the following comments regarding cord blood units.

There are a number of cord blood tissues banks now in operation. Ours has an FDA-approved IND (BB-IND #7520). I can envision that whatever rules that may come into effect may be different that the rules under which we have collected cord blood units prior to the effective date of that rule. I request that a provision be added for the units collected prior to the effective date of the rule to indicate tht such cord blood units be acceptable for human use. One could envision that a disclosure be provided to the transplant center requesting such a cord blood unit to indicate they were collected prior to the institution of the current regulations and that the requesting physicians agree to disclose all appropriate information to the recipient. This would prevent the destruction of this tissue donated in good faith by donors under IRB-approved informed consent and using the testing deemed appropriate at the time of their collection.

Secondly, in my opinion the proposed provision "recommending" that a 6 month follow-up infectious disease testing of the donor would be quite onerous and a further intrusion into the privacy of the donor and the mother. Further, I fear this would require needless destruction of a number of units collected if the donor (and mother) can not be contacted or if they do not agree to undergo the second set of testing. One might anticipate that this would have an undue effect on minority donors which may have less access to health care and may have a lower likelihood of being successfully contacted 6 months later. This would jeopardize one of the goals of cord blood tissue banks to provide hematopoietic stem cell sources to minority populations which are underrepresented in adult volunteer bone marrow registries. The proposed provision seems to put the safety standard for this tissue even higher than that required currently for blood donation without a scientific basis. The current measures (no 6 month quarantine and follow-up assessment) are at least as safe as the current blood donation procedures.

Third, under 1271.3. Definitions, a physical exam is mentioned "as being part of the required relevant medical records". I propose that this be construed to comprise an examination of the general appearance along with the history, vital signs, and an inspection that there are no physical stigmata of IV drug abuse and/or transfusion transmittable diseases. This would be in accordance with blood transfusion practices.

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Fourth, " 127 1.80 Donor testing; general rqeuirements", there is a proviso requiring infectious disease testing 48 hours after delivery. I propose a change to permit testing at some point within 48 hours prior to collection of cord blood to anytime afterward. This would provide testing for women at time of onset of labor at the time of other blood collection without subjecting them to the inconvenience and minor risk of a second venapuncture at a later time. Also, it is less likely that hemo-dilution issues pertinent to the ample would be of concern, Further, this would allow the proviso that if the blood collection did not take place prior to discharge, then it could be obtained after discharge at a follow-up visit. This should in no way reduce the accuracy of the testing.

Fifth, I request that the FDA give consideration to allow access of US citizens to cord blood units from foreign tissue banks. Such tissue banks would not do testing according to CLIA standards but would have similarly regulated clinical lab testing.

Thank you for your consideration.

Sincerely,

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Professor of Medicine and Pediatrics
Director, Bone Marrow Transplant Program
Associate Director, Clinical and Translational Research of Cancer Center
University of Florida College of Medicine

JRW/cmc